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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,553	ZHOU ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 9-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-36 are pending in the application. In the prior action, mailed on January 26, 2005, claims 5-8 were rejected, and claims 1-4 and 9-36 stood withdrawn as to non-elected inventions. In the Response, filed on July 19, 2005, the Applicant amended claims 5 and 7. Claims 5-8 are pending and under consideration. The Applicant has elected for examination inventions wherein the peptide comprises the sequence of SEQ ID NO: 19.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. **(Prior Rejection- Withdrawn)** Claims 5-8 were rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The claims were also rejected as lacking enablement because, by not providing a sufficient utility for the claimed inventions, the Applicant has not enabled those in the art to use the claimed invention. These claims broadly read on any peptides comprising a sequence according to the generic formula of SEQ ID NO: 3, or on peptides comprising SEQ ID NO: 19. First, it is noted that the P/CAF bromodomain does, as asserted by Applicant, fall within the scope of SEQ ID NO: 3 (as per the sequence listing of July 21, 2004). In view of the assertions in the application that the peptides may be used for the identification of drugs capable of treating either leukemia or HIV, the rejection is withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **(Prior Rejection- Maintained)** Claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims read on peptides comprising the ZA loop of protein bromodomains that fall within an indicated generic structure, that of SEQ ID NO: 3. The claims have also been amended to add the functional limitations that the peptides are useful for screening for inhibitors of interaction between a bromodomain and an acetylated lysine, and thereby in the identification of inhibitors of HIV replication or of tumor cell growth.

The Applicant traverses the rejection on the basis of teachings in the application regarding the association of the P/CAF bromodomain with the HIV Tat protein, and those in the November 2004 Declaration by Dr. Ming-Ming Zhou. These arguments have been considered but have not been found persuasive. While the Applicant may be enabled for the use of the P/CAF bromodomain, the application provides little if any guidance as to the use of other bromodomains. There is no specific identification of what diseases such other bromodomains may be associated with, or what acetyl-lysine containing peptides they may interact with. The specific teachings of both the application and the November 2004 Declaration are directed only

to the P/CAF- Tat protein interaction, and provide no guidance as to the use of the other bromodomain proteins.

Each of the Applicant's arguments in traversal amounts to an assertion that, because they have provided teachings regarding the potential use of the P/CAF bromodomain, those in the art would be enabled for the use of any ZA loop of any bromodomain. This assertion is not supported by the teachings of the art.

There are no teachings in the application regarding the elected embodiments, wherein the peptide comprises the ZA loop of SEQ ID NO: 19. While the art indicates that the RING3 protein, from which this sequence is derived, has some part in certain cancers, the relationship of the bromodomains of the protein to the cancers is not known or understood. See e.g., Denis et al., Cell Growth Diff 11: 417-24, at pages 417and 422. Thus, while the art indicates that bromodomains interact with acetyl-lysine containing proteins (Dhalluin et al. Nature 399, 491-96), it is not clear that an inhibitor of interaction between SEQ ID NO: 19 and its (unknown, but presumably acetyl-lysine containing) ligand would inhibit or induce cancer cell growth. See also, Guo et al, J Cell Sci 113:3085-91 (stating on page 3090 that it is not clear if the cancer inducing activities of RING3 are caused by up- or down-regulation of its ligands, and therefore making it unclear what effect inhibiting their association with RING3 would be). The art therefore supports an assertion that the RING3 protein is associated with cancers, but indicates that the functional relationship between the cancer and the protein is unknown, and indicates uncertainty in whether an inhibitor of protein activity would inhibit or aggravate the cancer.

In contrast to these teachings, the present application provides only teachings as to the interaction of an acetylated Tat protein with the bromodomain of P/CAF, and that certain

peptides comprising an acetylated lysine are also able to bind the P/CAF bromodomain. These teachings provide no guidance as to what proteins the RING3 bromodomains may interact with, or as to effects of such interaction (if any) on either HIV replication or cancer cell growth. Nor does the application provide such teachings for any of the other bromodomain containing proteins that may fall within the scope of the formula of SEQ ID NO: 3.

It is further noted that the application itself indicates that the binding partners of many bromodomains remain unknown. Page 3. There is no indication in the application that the binding capabilities of the P/CAF protein are representative of any bromodomain according to SEQ ID NO: 3. Further, the art supplied by the Applicant in traversal of the rejection would not support such a conclusion. For example, the teachings of the Mujtaba et al. reference (Exhibit B in the Response) indicate on page 583 that many of the residues involved in, and necessary for, P/CAF binding to Tat are not shared among the various other bromodomains of other proteins. Based on such teachings, those in the art would have no grounds for accepting that the binding of P/CAF to Tat is representative of the ability of bromodomains in general to do so.

Thus, as was indicated in the prior action, in contrast to the breadth of the claims, the teachings of the application are limited, and provide little guidance as to the use of the many various peptides falling within the scope of the claims. In view of the limited teachings in the application, the uncertainty in the uses for which the peptides may be applied, and the indication in the art as to uncertainty that those in the art would be able to use even the elected peptide as indicated by the claims and application, the rejection is maintained.

6. **(New Rejection- Necessitated by Amendment)** Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims are drawn to peptides useful for the screening of inhibitors of interaction between a bromodomain and an acetylated lysine. However, the application teaches that the bromodomain actually tested was not able to bind to a lone acetylated lysine. See, page 68. Further, the application provides rational for such a lack of binding that would indicate that no bromodomain according to the formula of SEQ ID NO: 3 would be capable of binding such lone acetylated lysines. Pages 68-69. In view of the teachings in the application that lone acetyl lysine does not bind to the bromodomains, the application is not enabling for peptides useful for the screening of inhibitors of such binding.

7. **(New Rejection- Necessitated by Amendment)** Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim s have been amended to read on isolated peptides comprising a ZA loop of a bromodomain, wherein such peptides are useful for the identification of agents that may be used to "prevent HIV replication." The Applicant is not enabled for such peptides.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re

Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, the factors considered most relevant is the scope of the claims, the guidance presented, the presence or absence of working examples, and the state and predictability of the art.

As indicated above, the claims are directed to peptides useful for the identification of agents that prevent HIV replication. While the application discloses examples of compounds that are disclosed as "particularly good candidates" as potential drugs, the application nowhere provides evidence that compounds identified using the claimed peptide would be capable of preventing HIV replication. Other than the suggestion of acetyl-lysine analogs as compounds that may be identified and that may have the ability to inhibit certain necessary functions of HIV and disclosure of the assay, the application provides no other guidance with respect to what other compounds may perform the requisite functions, or any evidence that any compounds identified through the use of disclosed method (using the claimed peptides) would prevent HIV replication. The application appears to at least implicitly assert that the identification of the assay and the function to be performed are sufficient to enable those in the art to practice the claimed methods of treating HIV infection using as yet undisclosed compounds.

In contrast to this implicit assertion in the application, the teachings in the art indicate that the identification of a desired target, and method for screening for compounds that perform the identified function, is not sufficient to allow those in the art to practice the claimed methods of treating HIV infection. Rather, the art provides several challenges being faced, and indicates an acceptance in the art that HIV therapy is an unpredictable art. The references describing the state of the art surrounding the therapy of HIV infection, even years after the present application was filed, indicates that, while there are treatments available for the disease, such treatments involve the use of multiple drugs targeting multiple phases of the viral life cycle simultaneously. See e.g., Marcus et al., Intervirology 45: 260-66, pages 263-64 (teaching that effective therapies require the use of multiple drugs, and that, due to the highly mutatgenic nature of the virus, it should expected that drug resistant varieties of virus will be present in every infected person); and Molla et al., Curr Opin Biotech 14:634-40, page 634 (noting that treatment of HIV infection with only one drug at a time, monotherapy, leads to rapid development of drug resistant strains). From these teachings, and the lack of any evidence regarding the efficacy of drugs identified using the peptides according to the claims, there is insufficient evidence to demonstrate that those in the art would be able to use individual drugs according to the claims to prevent HIV infection.

It is also noted that, with that the claims identify the peptides as capable of screening for agents inhibiting interaction between a bromodomain and an acetylated lysine. The claims are not limited to any specific bromodomain of a particular protein, or to any specific sequence comprising an acetyl-lysine. With respect to such embodiments, the specification provides an unsupported assertion that these compounds share the "critical feature" of falling within the

formula of Figure 12. However, the disclosure fails to provide any evidence of the criticality of this feature. I.e., there is no experimental data demonstrating that any compound according to this formula is able to inhibit the interaction, and even contradicts the assertion by explicitly stating that these compounds as merely "particularly good candidates" as anti-HIV drugs. Page 44, lines 11-17. More particularly, the specification provides further grounds for questioning the utility of an inhibitor of any acetyl-lysine from binding a bromodomain by the disclosure of pages 68-69, indicating that a lone acetyl-lysine was incapable of binding to a bromodomain.

While the art and the application teach that the bromodomain of P/CAF binds to an acetylated lysine on Tat, and that this acetylation is required for Tat-P/CAF binding, it is not clear that any acetyl-lysine would be capable both of binding to P/CAF, or of inhibiting Tat-P/CAF interaction. For example, Zeng et al. (FEBS Letters 513:124-128) teaches that the bromodomains do not interact solely with the acetyl-lysine, but that the specificity of such binding also relies on the presence of other residues flanking the acetyl-lysine. Such teachings are supported by the specification, which states on page 68-69 that lone acetyl lysine was not able to bind to a bromodomain, and that such binding appears to be specific to certain peptides comprising an acetyl-lysine. Thus, it is not clear that the presence of any acetyl-lysine analog would be sufficient to overcome the preferential binding of Tat to P/CAF. In view of this uncertainty, and the lack of any evidence to demonstrate that such compounds would both be capable of inhibiting Tat-P/CAF interaction, and treating viral infection by this mechanism, this unsupported assertion of a critical feature is not sufficient to enable the use of such analogs in the claimed methods.

Further, the Applicant has not elected, as the species for consideration, embodiments wherein the bromodomain is from P/CAF. Rather, the Applicant has elected the bromodomain of SEQ ID NO: 19, which is from the hsRING3 protein. There is no evidence in the application or indication in the art that this sequence binds to Tat, or to any HIV protein, or that inhibition between the binding of this sequence with any acetyl-lysine analog would have any effect on the progression of HIV infection. Because the application provides no evidence that any bromodomain other than that of P/CAF would have any association with HIV, and because the application has not established that any, or identified which, acetyl-lysine analogs would be capable of preventing HIV replication, the claims are rejected as exceeding the scope of enablement.

8. **(New Rejection- Necessitated by Amendment)** Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection. These claims have been amended to read on peptides useful for screening for inhibitors that may be used to "inhibit tumor cell growth." However, while the application provides antecedent basis support for embodiments wherein the inhibitor is useful for the treatment of cancers (page 20) there is no support in the application for embodiments wherein the inhibitors identified by the disclosed methods may be used to "inhibit tumor cell growth." Applicant is required to either

cancel the New Matter from the application, or to point out where support for such may be found in the application.

9. **(New Rejection- Necessitated by Amendment)** Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims read on isolated peptides comprising the ZA loop of a bromodomain, particularly to bromodomains of the formula of SEQ ID NO: 3, and more particularly to that of the RING3 protein (SEQ ID NO: 19), wherein such peptides may be used for screening of inhibitors of binding between the bromodomain and an acetylated lysine, and wherein such inhibitors inhibit tumor cell growth. The Applicant is not enabled for the claimed peptides.

It is first noted that the art indicates that the RING3 protein, from which the ZA loop of SEQ ID NO: 19 is derived, does have some association with certain cancers or tumors. See e.g., Guo et al., supra. However, as was indicated above, the teachings of the art also indicate uncertainty in the functional relationship between the protein and cancer; i.e. it is not clear if an inhibitor of RING3 ligand interaction would inhibit or aggravate cancer cell growth. Because the application provides no guidance or evidence to allow those in the art to determine the effect of an inhibitor on RING3 interaction with its ligands on cancers, the Applicant has not enabled those in the art to use the claimed peptides.

Further, the application provides teachings relating only one of the other disclosed peptides with cancer- the CBP bromodomain. App., page 20. The application provides no

guidance as to which other of the peptides falling within SEQ ID NO: 3 would be useful for the identification of inhibitors of cancer growth. The application neither identifies specific proteins that are associated with cancers, nor provides any guidance as to the functions of such other proteins.

In contrast to these limited teachings, the art teaches that different bromodomain containing proteins perform different functions. See e.g., Jeanmougin et al., Trends Biochem Sci 22: 151-153. Further, the art also teaches that different bromodomains in the same proteins may also perform different functions. Guo, pages 151-152. The fact that two of the indicated bromodomains have been shown to be associated with certain cancers does not, in view of the different activities of the various bromodomains, establish that any protein comprising a ZA loop within the formula of SEQ ID NO: 3 would also 1) have such an association and 2) be useful for the identification of cancer growth inhibitors. As the application provides insufficient guidance as to which bromodomains are associated with cancers, and as to which would be useful for the identification of inhibitors for those cancers, and in view of limited teachings in the art, and uncertainty in the art as to the effects of inhibiting bromodomain/ligand interactions on cancer, the application has not provided adequate information to enable those in the art to use the full scope of the claimed peptides.

10. **(New Rejection- Necessitated by Amendment)** Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. These claims are drawn to a genus of peptides identified by their falling within the formula of SEQ ID NO: 3, and by their functional activity as useful for the identification of inhibitors of HIV replication or tumor cell growth.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed. In the present case, the application provides several examples of peptides falling within the scope of SEQ ID NO: 3. See e.g., Figure 1. The application also provides examples of ligands for two of these peptides. Pages 20-21. Of the disclosed peptides, the Applicant has disclosed one as useful for identifying inhibitors of HIV replication (the P/CAF peptide), and one as potentially useful for the inhibition of cancers (the CBP peptide). Id. However, the application does not demonstrate that every peptide according to SEQ ID NO: 3 is capable of the indicated uses. While SEQ ID NO: 3

identifies a common sequence to many of the disclosed peptides, there has been no correlation drawn between the presence of the sequence and the utility of the peptide in the identification of inhibitors of either cancer growth or HIV replication.

The application teaches that one peptide may be used to identify inhibitors of HIV replication, and another may be a potential target for the treatment of leukemia. However, these are two different unrelated functions. The fact that a different peptide from the formula of SEQ ID NO: 3 has been implicated in these two different disorders is not sufficient to demonstrate that any peptide falling within SEQ ID NO: 3 would be useful in one of these two functions. Rather, as was indicated above, the art teaches that the different bromodomains are likely to perform different functions, and interact with different proteins, based on the presence of different amino acids in the sequences. See e.g., the Mujtaba et al reference cited by the Applicant in Exhibit B. See also, Jeanmougin et al., Trends Biochem Sci 22: 151-153 (teaching different functions of different bromodomain containing proteins, several of which are identified in Figure 1 of the present application). Thus, bromodomains according to SEQ ID NO: 3 may be found in different proteins that perform many different functions. There has been no demonstration that each of these proteins would be useful for the identification of at least one of the two types of inhibitors required by the claims. In view of the uncertainty in ability of such other proteins to operate for the identification of such inhibitors, and the lack of any correlation between this function and the formula of SEQ ID NO: 3, the Applicant has not provided adequate written description support for the claimed genus of inventions.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **(Prior Rejection- Withdrawn)** Claims 5 and 6 were rejected under 35 U.S.C. 102(a) as being anticipated by Dhalluin et al. (Nature 399:491-96- of record in the July 2002 IDS). In view of the Applicant's submission of a declaration under 35 U.S.C. 132 by Dr. Zhou, indicating that the applied teachings of Dhalluin et al. was the work of the named inventors of the present application, the rejection is withdrawn.

13. **(Prior Rejection- Maintained)** Claims 5 and 6 were rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al., Nature 382: 319-24. The claims have been amended to read on a peptide comprising a ZA loop of a bromodomain, wherein the ZA loop consists of SEQ ID NO: 3. It is noted that the claim places no limitations on what other sequences may be present in the peptide other than the ZA loop. Thus, the claim reads on any peptide comprising a sequence according to SEQ ID NO: 3. As indicated in the prior action, Yang teaches a fusion protein of P/CAF with a FLAG epitope, wherein the polypeptide includes SEQ ID NO: 3. The Applicant presents three arguments in traversal.

The Applicant first argues that the reference does not teach or suggest a peptide comprising SEQ ID NO: 3, with the bromodomain of SEQ ID NO: 19. As the rejection was applied only against claims 5 and 6, neither of which recites the sequence of SEQ ID NO: 19,

applicant's arguments that the reference does not teach this sequence is not found persuasive. The rejected claims nowhere present a limitation to peptides comprising SEQ ID NO: 19. The Applicant is therefore arguing a limitation not found in the claims. Such is not persuasive to avoid the rejection.

The Applicant further asserts that the reference does not teach that the peptides may be used to screen for drugs that inhibit interaction between the bromodomain and acetyl-lysine, and provides other functional language. However, the claims are directed to an isolated peptide, and not to a method of using such. Thus, the functional language is treated merely as describing an intended use of the peptide. There has been no suggestion that the peptide of Yang could not be used in such methods. Further, there is no disclosure of any structural distinction between the peptide of Yang and that of the present claims. The Applicant's arguments in traversal are therefore not found persuasive. Because the peptide of Yang meets the structural limitations of the claimed peptides, the rejection is maintained.

The Applicant's third argument in traversal is that the claims have been limited to peptides "consisting" rather than "comprising." While claim 5 has been amended to insert a "consisting" phrase, this is not a complete description of what is claimed. As indicated above, the claim is directed to any peptide comprising a ZA loop consisting of SEQ ID NO: 3. The claim does not however provide any limitation as to what the other sequences of the peptide may comprise. Thus, the claims read on any peptide comprising SEQ ID NO: 3. As indicated above, Yang teaches such a peptide. Because the claim is not limited to peptides consisting of SEQ ID NO: 3.

The rejection is therefore maintained for the reasons above, and the reasons of record.

14. **(Prior Rejection- Maintained)** Claims 5-8 were rejected under 35 U.S.C. 102(b) as anticipated by Denis and Green (Genes Dev 10(3): 261-71). The claims and the teachings of Denis and Green have been previously described. The Applicant traverses the rejection on two grounds. However, it is noted that the Applicant's arguments have, incorrectly, stated that only claims 5 and 6 were rejected over this reference. However, each of claims 5 to 8 were cited as rejected in the prior action.

The Applicant's first argument in traversal is that claims 5 and 6 do not read on SEQ ID NO: 19. This argument is not found persuasive. As indicated above, the claims read on any peptide comprising a sequence according to the formula of SEQ ID NO: 3. SEQ ID NO: 19 comprises such a sequence. Because Davis and Green teaches a peptide comprising this sequence, the reference meets the structural limitations of the claimed peptides.

The Applicant's second argument in traversal is substantially identical to the second argument presented above with respect to the Yang reference (i.e. the added functional language). As the functional language merely represents an intended use of the peptides, and does not provide any structural distinction between the claimed peptides and those disclosed by the art, the argument is not found persuasive.

The rejection is therefore maintained for the reasons above, and the reasons of record.

Conclusion

15. No claims are allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 8/8/05
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600